IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

OAK HILL HOMETOWN PHARMACY,

Petitioner,

CASE NO. 2:19-cv-00716

v.

UTTAM DHILLON, in his official capacity as Acting Administrator; and UNITED STATES DRUG ENFORCEMENT ADMINISTRATION,

Respondents.

MEMORANDUM IN SUPPORT OF MOTION FOR TEMPORARY RESTRAINING ORDER

On August 8, 2019, agents with the United States Drug Enforcement Administration ("DEA") raided Oak Hill Hometown Pharmacy ("OHHP"), a community pharmacy in Oak Hill, West Virginia. With firearms brandished, those agents served on OHHP an *ex parte* Order to Show Cause and Immediate Suspension of Registration ("Ex Parte Suspension Order") issued by Acting Administrator Uttam Dhillon ("Administrator") on August 6, 2019. That Ex Parte Suspension Order caused two different and separate results. First, it put OHHP on notice that the DEA was seeking to revoke its Certificate of Registration ("Registration") which would be the subject of forthcoming administrative proceedings. Second, the Ex Parte Suspension Order immediately suspended OHHP's Registration pending the eventual determination regarding revocation. In essence, there are two outcomes, revocation, for which a party is entitled to a hearing an opportunity to respond before being deprived of its DEA registration, and immediate suspension, for which OHHP may only obtain review in this Court.

The Ex Parte Suspension Order based each of those outcomes upon one of two preliminary findings reached by the Administrator. The first preliminary finding went to the revocation and provided that OHHP had filled Subutex prescriptions inconsistent with the public interest, requiring OHHP's response to the DEA's allegations to explain why its Registration should not be revoked under 21 U.S.C. §§ 823(f), 824(a)(4)&(c) ("Show Cause Finding"). The second preliminary finding went to the immediate suspension and asserted that OHHP's Registration was immediately suspended because its continued registration "constitute[s] 'an imminent danger to the public health or safety,'" pursuant to § 824(d) ("Preliminary Immediate Suspension Finding"). *See* Exhibit 2, *Ex Parte Suspension Order*, at 12. According to the Ex Parte Suspension Order, the Preliminary Immediate Suspension Finding was based on "the substantial likelihood that OHHP will continue to unlawfully prescribe controlled substances, thereby allowing the diversion of controlled substances, unless OHHP's [Registration] is suspended." *See id.* Due to that Preliminary Immediate Suspension Finding, agents confiscated OHHP's Registration and seized all of OHHP's scheduled medications, thus instantly depriving OHHP of the valuable ability to fill its patient's scheduled medications.[1]

[1] The Ex Parte Suspension Order does not constitute a final agency action for purposes of the Administrative Procedures Act ("APA"), 5 U.S.C. § 701 *et seq.* A final order is only reached in a DEA enforcement proceeding after the Administrator has received the Administrative Law Judge's ("ALJ") recommended findings of fact, recommended conclusions of law, and recommended decision. *See* 21 C.F.R. § 1316.67 (providing that the Administrator must issue a final order setting forth final rule, the findings of fact, and conclusions of law); *see also id.* at §1316.65 (explaining that the ALJ shall prepare recommended findings of fact and conclusions of law and a recommended decision for the Administrator after the hearing is held and the parties have submitted their proposals). Because the Ex Parte Suspension Order is not a final agency action, the APA, and its associated standard of review, does not apply. *See* 5 U.S.C. § 704 (making only final agency actions reviewable under APA); *see also U.S. Army Corps of Engineers v. Hawkes Co., Inc.*, 136 S. Ct. 1807, 1813 (2016) (explaining that final agency action reviewable by judiciary requires "the consummation of the agency's decisionmaking process — it must not be of a merely tentative or interlocutory nature" (citation and internal quotation marks omitted)). Moreover, as (Continued)

OHHP seeks only the dissolution of the immediate suspension of its Registration by this Court.[2] In order to dissolve that immediate suspension, this Court need only reach a determination regarding the sufficiency of the Administrator's Preliminary Immediate Suspension Finding. Moreover, this Court — not an ALJ — is the forum to review that finding and the accompanying immediate suspension of a certification registration. *See Norman Bridge Drug Co. v. Banner*, 529 F.2d 822, 823-24 (5th Cir. 1976) (explaining that "plain language" of §824(d) "means that one faced with becoming the victim of the harsh expedient of suspension without prior notice may resort to the appropriate district court in search of appropriate relief"). Because the Ex Parte Suspension Order, and its Preliminary Immediate Suspension Finding, failed to satisfy the statutory standard for immediate suspension in 21 U.S.C. § 824(d), this Court should dissolve the immediate suspension and restore OHHA's Registration forthwith.

I. FACTUAL BACKGROUND

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provided in the specific statutory provisions applicable to DEA administrative proceedings, only "final" determinations are reviewable by a federal court of appeals. *See* 21 U.S.C. § 877. This Court, as a district court of competent jurisdiction, is the proper forum to review the Administrator's immediate suspension of OHHP's Registration. *See Novelty Distrib., Inc. v. Leonhart,* 562 F.Supp.2d 20, 28 (D.D.C. 2008) (concluding that district court had jurisdiction to hear challenge to DEA's action under § 824(d) because such action was not final agency action).

[2] To be clear, OHHP does not challenge the Show Cause Finding or the potential revocation of its Registration in this forum. That finding, and any potential revocation, is the subject of administrative proceedings currently before a DEA ALJ. Although the ALJ is the proper forum for litigating the Show Cause Finding and the DEA's alleged basis for revocation, § 824(d) authorizes review and dissolution of an immediate suspension "by a court of competent jurisdiction." *See* 21 U.S.C. § 824(d). Therefore, OHHP's petition for this Court to dissolve the immediate suspension, and request for immediate reinstatement of its Registration, pending the administrative hearing regarding potential revocation, is statutorily permitted. Indeed, DEA ALJs have recognized that they do not possess the statutory authority to review an immediate suspension of a certificate of registration. *See Barry M. Schultz, M.D.*; Decision and Order, 76 Fed. Reg. 78,695, 78,697 (Dec. 19, 2011) ("[T]o the extent that the Respondent believes that the agency's immediate suspension of [his] registration was inappropriate, either substantively or procedurally, that matter is not reviewable by this tribunal, and must be pursued in the federal District Court.") (citing 21 U.S.C. § 824(d)).

A. OHHP begins serving its community and helps fight opioid use disorder by filling medications to treat that disorder.

OHHP has been a staple of the Oak Hill community since its inception in 2012. As a locally owned, family business, OHHP serves patients from Oak Hill and its surrounding areas. In short, OHHP was the fulfilment of a longtime goal of its part owner and head pharmacist, Martin Njoku, who has lived and worked as a pharmacist in that area for nearly thirty years. And shortly after its inception, OHHP's patient base soon began to grow. In 2016, historic and catastrophic floods left much of Greenbrier and Nicholas Counties underwater and its businesses closed. As a result, patients from those and other affected counties began filling their prescriptions at OHHP.

Like many businesses in West Virginia, especially those in the southern part of the State, the opioid epidemic also began to affect OHHP's business. In response to the epidemic, and in an effort to help remedy the deep scars that it has left on the community, OHHP filled prescriptions for a common medication, called Subutex, which was specifically approved by the FDA to treat patients with opioid use disorder. Subutex prevents withdrawals for those dependent on opioids and allows them to begin to reenter the workforce. Subutex is the brand name for a medication that contains only one active ingredient, buprenorphine. Buprenorphine attaches to opioid receptors, thus preventing the feeling of withdrawal. But unlike opiate street drugs, buprenorphine does not produce the same euphoric feeling or "high." *See* Exhibit 3, *Declaration of Martin Njoku*, at ¶ 3. Thus, it is well positioned to simultaneously prevent opioid dependent patients from experience excruciating withdrawal and permit those patients to live more productive and healthy lives.

But because of the stigma associated with treating patients suffering from addiction, many pharmacies declined to stock Subutex. Although Subutex is FDA-approved for use in what is referred to as Medication Assisted Treatment ("MAT") of opioid use disorder, many pharmacies

refused to fill Subutex prescriptions. That refusal was primarily due to the stigma associated with Subutex and the patients who take it. In lieu of Subutex, some, but not all, of those pharmacies would fill another prescription written by physicians as part of MAT — Suboxone.

Suboxone is the brand name of a medication that combines buprenorphine and naloxone. With the addition of naloxone, which is an opioid antagonist, Suboxone is intended to be formulated to decrease the ability of patients to potentially misuse the buprenorphine. Suboxone's efficacy in that respect, however, has not been clearly demonstrated and is a point of medical discussion. In addition to both Subutex and Suboxone being FDA-approved for MAT, Subutex was often cheaper for patients than Suboxone — due partially to the fact that it had a generic version and Suboxone did not until late 2018. *See* Exhibit 3, at ¶ 4.

B. DEA serves an administrative warrant in November 2018 and interrogates OHHP employees on its practices related to filling Subutex, after which OHHP substantially reduced filling of Subutex prescriptions.

On November 28, 2018, DEA agents served an administrative warrant on OHHP. As part of that warrant, agents interviewed employees of the pharmacy and inspected its records. But the warrant, as well as the agents' investigation, focused solely on OHHP's filling of Subutex prescriptions, nothing else. During their interviews and inspections, agents claimed that so-called "red flags of diversion" were present in OHHP's filling of Subutex. In DEA parlance, such "red flags" should cause a physician or a pharmacy to inquire further into the legitimacy of a prescription. But as OHHP employees explained to the DEA agents during their interviews, none of the supposed "red flags" identified by those agents were actually red flags of diversion. And to the extent that they were red flags, OHHP was diligently detecting and resolving them.

The DEA agents expressed three primary concerns about the Subutex prescriptions filled by OHHP: (1) distance travelled by the patients, (2) the selection of Subutex rather than Suboxone;

and (3) private pay for partial fills of the prescriptions. With regard to the first, distance, the DEA agents expressed concern that patients from West Virginia were travelling to Pennsylvania to seek MAT and that patients were traveling anywhere from fifteen to fifty miles from their homes to OHHP in order to fill their prescriptions. Those concerns were premised upon the implication that patients would only travel such distances if something illicit was afoot, and therefore the travel was a red flag. Regarding the second category, agents worried that Subutex itself — despite being an FDA-approved medication to treat opioid use disorder — was a red flag that patients were diverting that medication for illicit purposes. Finally, DEA agents noted that many patients purchased only part of their prescription at any one time and did so without insurance covering any of that cost.

But the OHHP staff explained to DEA agents that they misunderstood the situation on the ground in rural West Virginia; neither the distance, the medication, nor the private payment for partial fills was a red flag. Instead, those characteristics were created by legitimate but unfortunate circumstances surrounding the treatment of opioid-dependent patients. In short, they were not indications of illicit diversion at all.

The OHHP staff explained that there were multiple reasons for the distance travelled by MAT patients. The staff described how there were simply not enough MAT providers in West Virginia. In order to administer MAT, a provider must obtain special DEA permission to prescribe medications for opioid use disorder. *See* 21 U.S.C. § 823(g). There were many counties in the State — including those near Oak Hill — where there *was not a single* MAT provider in the entire county. *See* Exhibit 4, *Letter from West Virginia Board of Pharmacy*, at 2. But even in the areas where there were MAT providers, many were not accepting new patients and wait times to see those providers could be many months. Indeed, the number of MAT patients a provider can see is

limited by Congress. *See* 21 U.S.C. § 823(g)(2)(B)(iii). And if a patient was lucky enough to find a provider who was accepting new patients, that treatment was often not covered by patient's insurance and was unaffordable to pay out of pocket. Because of the abundance of MAT providers in Pennsylvania, however, it was much easier for patients to get into a treatment program there. Plus, the Pennsylvania providers were more affordable and required fewer in-office visits, which meant that MAT patients could maintain their job and go to their MAT provider once or twice a month. By contrast, it was not uncommon for providers in West Virginia to require appointments weekly, or more often, which made it nearly impossible to hold a job while getting treatment. In short, Pennsylvania providers were more available, more affordable, and more workable. Going to those providers was not a red flag, it was instead a helpful step toward treatment and recovery from opioid dependence.

Likewise, the OHHP staff explained that the distance travelled by patients to OHHP was a product of West Virginia and its communities. For one, much of West Virginia and the area surrounding Oak Hill is rural and a lot of people in that area live a long way from businesses like pharmacies. Just to get to a convenience store can require miles and miles of driving on mountainous, curvy roads. Even if patients lived in communities with a pharmacy, many pharmacies in the State refused to fill Subutex because of the stigma associated with it and those who take it — that is, patients suffering from addiction and opioid use disorder. Assuming, however, that a patient was able to find a pharmacy close to them that did fill Subutex, some patients chose not to frequent those pharmacies for fear that news of their treatment status would spread throughout their small communities.

Turning to the second supposed red flag — the medication itself, Subutex — the OHHP staff dispelled that concern as well. The DEA agents expressed concern that Subutex and not

Suboxone was being prescribed and filled. According to the DEA, Suboxone was a more appropriate medication for MAT and in most cases, Subutex had no legitimate medical use. But Subutex is and was an FDA-approved medication for use in MAT, the exact treatment for which the patients at OHHP were filling their Subutex prescriptions. Moreover, Subutex was more affordable than Suboxone. Because health insurance would not cover those patients' MAT prescriptions, cost was a legitimate concern of patients who were trying to get help for their opioid use disorder. That legitimate cost concern also explained why patients often only purchased partial fills of their Subutex prescriptions and dispelled the DEA's third red-flag concern. Patients would receive partial fills at regular intervals as they could afford, instead of getting their full Subutex prescriptions at one time. With insurance refusing to cover those prescriptions, most patients could simply not afford to fill their entire prescription at once.

After the DEA served the administrative warrant, OHHP sought to reduce its filling of Subutex prescriptions. Although OHHP and its staff did not believe that it had left any potential red flags unresolved, Dr. Njoku and OHHP made the decision to exercise excess caution. OHHP still wished, however, to help combat the opioid epidemic. So, OHHP decided to only fill Subutex prescriptions for a select group of roughly 20 patients after that November 2018 administrative warrant. And by January of 2019, OHHP had further reduced that to just seven patients — multiple pregnant woman, people who could not take Suboxone because of an allergy or adverse health impacts, and a single cancer patient who received the medication for pain, not addiction.

C. OHHP fills new Subutex prescriptions for small select group of patients in need and DEA immediately suspended OHHP's registration without notice or an opportunity to respond.

OHHP continued to fill Subutex prescriptions for that select group of seven patients until August 8, 2019, when DEA agents again entered OHHP. From January 1, 2019 until the DEA

arrived at OHHP again, OHHP had filled a total of 68 Subutex prescriptions for that group of patients. *See* Exhibit 3, at ¶ 21. But this time when they entered, those agents did not merely serve an administrative warrant and interview OHHP's employees. Instead, they served the Ex Parte Suspension Order, seized OHHP's Registration, confiscated its controlled substances, and effectively shut down OHHP's pharmacy business.

The Ex Parte Suspension Order generally alleged that OHHP continued to improperly dispense Subutex *after* the November inspection. That allegation was based on the same supposed red flags that the DEA agents had discussed with the OHHP staff back in November: the prescriptions were for Subutex and not Suboxone; those prescriptions were written by out of state providers, whose patients had travelled a sizeable distance to visit them and who were treating multiple West Virginia patients on the same day; the prescriptions were paid privately and without insurance (or, as the Government likes to call it, "paid for in cash," even though those "cash" payments include those made with cash, checks, debt cards, and credit cards); the patients travelled to fill their prescriptions at OHHP; and that OHHP filled, over a multi-year period, an average of seven of those prescriptions a day. According to the Ex Parte Suspension Order — despite the reasonable and real-life explanations provided by the OHHP staff for each of those concerns — those were red flags that "were highly indicative of abuse and diversion." *See* Exhibit 2, at 8.

The Ex Parte Suspension Order also identified that OHHP had continued to fill Subutex prescriptions "through at least March 2019," which the Government referred to as "ongoing conduct." *See* Exhibit 2, at 8. That order repeated all of the same red flags that were supposedly raised by filling those Subutex prescriptions. The Ex Parte Suspension Order asserted that the Government's expert had reviewed 43 Subutex prescriptions that OHHP had filled from December 2018 to March 2019 — that is, an average of about 10 Subutex prescriptions *a month* — and that

those prescriptions presented the same red flags as before. Finally, the Ex Parte Suspension Order contended that there is "no legitimate need for Subutex." *See id.* at 10.

Based on those allegations, the Administrator who issued the Ex Parte Suspension Order reached its two preliminary findings. The first preliminary finding, the Show Cause Finding, went to the standard provided in 21 U.S.C. § 824(c), which requires that before revoking a pharmacy's registration, the DEA must serve upon it "an order to show cause as to why registration should not be . . . revoked." *See* 21 U.S.C. § 824(c). That section does not permit, however, the revocation or suspension of a registration before that pharmacy has had the opportunity to respond to the allegations either by "a corrective action plan" or an administrative proceeding. *See id.* In other words, the typical procedure for revoking or suspending a registration requires notice and an opportunity to be heard.

But by way of his second preliminary finding — the Immediate Suspension Finding — the Administrator sought to immediately suspend OHHP's Registration without permitting it the opportunity to respond. That preliminary finding read as follows:

> significantly in light of the rampant and deadly problem of prescription controlled substance abuse, that OHHP's continued registration during the pendency of these proceedings would constitute "an imminent danger to the public health or safety" because of the substantial likelihood that OHHP will continue to unlawfully *prescribe* controlled substances, thereby allowing the diversion of controlled substances, unless OHHP's [Registration] is suspended.

See Exhibit 2, at 12 (emphasis added). The Administrator, based on that preliminary finding, immediately suspended OHHP's Registration pursuant to 21 U.S.C. § 824(d). Section 824(d) permits the DEA Administrator to suspend, *ex parte*, any registration where "he finds that there is an imminent danger to the public health or safety." *See* 21 U.S.C. § 824(d); *see also* 21 C.F.R.

§ 1301.36(e). Importantly, the statute provides a definition of "imminent danger to the public health or safety," which means that

> due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations . . . there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in absence of an immediate suspension of the registration."

See id. at §824(d)(2). In order to immediately suspend a registration under that provision, the Administrator must provide "a statement of his findings regarding the danger to public health or safety." *See* 21 C.F.R. § 1301.36(e). And a suspension under that section continues until "withdrawn by the Attorney General or dissolved by a court of competent jurisdiction." *See id.*[3] In essence, an immediate suspension — without notice or an opportunity to be heard — is appropriate in the extraordinary, not merely ordinary situation.

Consistent with the immediate suspension of OHHP's Registration, the DEA agents confiscated all of OHHP's controlled medications and effectively halted its ability to serve as complete pharmacy for its patients. OHHP was not permitted an opportunity to respond to those allegations prior to DEA's actions or explain its diligent detection and resolution of potential warning signs of diversion.

D. OHHP business is crippled, it is forced to lay off employees, and faces impending closure.

Left without a certificate of registration to fill any prescriptions for controlled medications, OHHP quickly began to lose patients. Other patients were scared away by the press and media blitz conducted by the Government against OHHP. The Government issued a press release that contained salacious-sounding allegations about OHHP's filing of Subutex; the United States

[3] Pursuant to regulations, the Attorney General has delegated his duties to the Administrator of the DEA. *See* 28 C.F.R. § 0.100.

Attorney for the Southern District of West Virginia contemporaneously tweeted about the action against OHHP from his official and personal twitter accounts.

Unable to respond to those attacks, and despite only trying to aid in the MAT of patients who were seeking help with their opioid use disorder, OHHP's business started to shrivel. It quickly had to lay off employees, received threats from its distributors that it would be cut off from further medication orders, and had to take out a line of credit just to keep the lights on. *See* Exhibit 3, at ¶ 22. Given this state of affairs and the financial pressures — as attested to by OHHP's part owner, Dr. Njoku — OHHP will likely close in the very near future, without some resolution or reinstatement of its Registration. *See id.*

E. OHHP obtains confirmation that DEA knew or should have known, at the time, that the factual allegations supporting the Ex Parte Suspension Order were false.

Before filing this case, OHHP sought to obtain the Prescription Data Monitoring Program ("PDMP") data on which the DEA relied in issuing the Ex Parte Suspension Order. Although the United States Attorney's Office for the Southern District of West Virginia initially expressed a willingness to provide that data in conjunction with its own separate civil investigation, it was countermanded by the DEA lawyers in the Administrative Proceeding who refused to provide the PDMP data other than in a completely unusable format. Over the DEA's strenuous objection, the ALJ in that Administrative Proceeding ordered the government to produce the PDMP data in a useable, excel format, and did so after OHHP had already filed this action. Having obtained the PDMP Data in a useable format, OHHP has been able to confirm the following:

- The DEA's *ex parte* suspension was predicated on false allegations of "ongoing conduct" detailed on pages 8-10 of the *ex parte* suspension order. ECF No. 1-2, at 8-10.

- The ongoing conduct included false allegations that OHHP "temporarily curtailed," and then "resumed" filling allegedly suspicious prescriptions after the DEA's November 28, 2018 execution of an Administrative Inspection Warrant ("AIW").

- More specifically, the *ex parte* suspension order alleges that a "DEA Expert reviewed 43 prescriptions" that OHHP filled from December 2018 to March 2019 for out-of-State Subutex. ECF No. 1-2, at ¶12.

    - The truth, which the DEA knew at the time and withheld, is that OHHP accepted a total of 11 new out-of-State Suboxone prescriptions after the AIW and that those eleven prescriptions were issued to a *total of 3 patients*: **N.R., M.V.**, and **J.J.2.**

    - Patient **N.R.** was permitted to fill a single Subutex prescription which was issued on November 29, 2018, the day immediately following the AIW. **N.R.**'s pharmacy record reflects that on that date she was told "this will be the last RX we will take for this medication." That was the last Subutex prescription filled by OHHP for **N.R.**

    - Similarly, patient **M.V**. was permitted to fill a single Subutex prescription which was issued on November 29, 2018, the day immediately following the AIW. **M.V.**'s pharmacy record also reflects that on that date she "was told by Martin no longer filling Subutex." That was the last Subutex prescription filled by OHHP for **M.V.**

    - Patient **J.J.2** *is the only Subutex patient who was permitted to fill additional new out-of-State prescriptions issued after the AIW*. OHHP's pharmacy records reflect that this is because **J.J.2** was pregnant.

    - In other words, OHHP has confirmed that the DEA knew, at the time of the *Ex Parte* Suspension Order, that (1) after the AIW OHHP accepted a total of 11 new out-of-State Subutex prescriptions, (2) that those new out-of-State Subutex prescriptions were issued to a total of three patients, (3) that two of them (**N.R.** and **M.V.**) were one-time-only prescriptions issued the day after the AIW, and (4) that only one patient (**J.J.2**) was permitted to continue filling out-of-State Subutex prescriptions. At that time, **J.J.2** was pregnant.

- Aside from the prescriptions issued to **N.R., M.V.**, and **J.J.2.**, OHHP permitted 19 patients with out-of-State Subutex prescriptions to obtain the balance of prescriptions which had been partially filled prior to the AIW. For these patients, OHHP *did not accept a single new out-of-State Subutex prescription after the AIW*. Rather, OHHP permitted them to obtain the remainder of prescriptions which had been partially filled before the November 28, 2019 AIW:

	RX #	Patient	Gender	Initial Fill Date
1	160986	N.P.	F	September 5, 2018
2	166451	J.F.	M	November 12, 2018
3	166459	M.H.	F	November 12, 2018

4	166751	J.U.	M	November 14, 2018
5	166788	K.F.	F	November 14, 2018
6	166889	S.N.	M	November 15, 2018
7	167023	J.J.2	F	November 16, 2018
8	167030	K.S.	F	November 17, 2018
9	167041	R.M.	M	November 17, 2018
10	167042	R.L.M.	M	November 17, 2018
11	167050	J.P.	M	November 19, 2018
12	167061	W.F.	M	November 19, 2018
13	167062	N.J.	F	November 19, 2018
14	167093	J.W.	M	November 19, 2018
15	167100	R.D.	M	November 19, 2018
16	167275	D.T.	M	November 20, 2018
17	167397	S.D.	M	November 21, 2018
18	167523	S.H.	F	November 26, 2018
19	167651	W.H.	F	November 27, 2018

- Finally, the *Ex Parte* suspension order claims that from December 2018 through March 2019, OHHP filled 21 out-of-State Subutex prescriptions that were written for male patients. The truth, which DEA knew at the time, is that 11 male patients were among those permitted to obtain the balance of their prescriptions after the AIW, *but that OHHP did not accept a single new out-of-State Subutex prescription written for a male patient after the AIW*. *See* Exhibit 2, at 8.

OHHP was only able to confirm the foregoing after obtaining the PDMP Data relied upon by the DEA in the preparation and issuance of the Ex Parte Suspension Order — over the refusal and strenuous objections of the DEA and the United States Attorney's Office for the Southern District of West Virginia.

II. ARGUMENT

The Administrator's basis for his *ex parte*, immediate suspension of OHHP's Registration was woefully insufficient and was based upon factual allegations which the DEA knew or should have known at the time to be false. Not only did the Administrator effectively shut down OHHP's business based upon mistaken views of real-life circumstances in West Virginia, but he also simply got many of those facts *wrong*.

Because OHHP meets the requirements for temporary relief, this Court should dissolve the immediate suspension and reinstate and restore OHHP's Registration. In order obtain a temporary restraining order ("TRO"), a plaintiff must demonstrate four elements: (A) that it is "likely to succeed on the merits;" (B) that it "will likely suffer irreparable harm absent an injunction;" (C) that "the balance of hardships weigh in [its] favor;" and (D) that "the injunction is in the public interest." *See League of Women Voters of N.C. v. N.C.*, 769 F.3d 224, 236 (4th Cir. 2014); *see also Marfork Coal Co. v. Smith*, No. 5:10-cv-00069, 2010 WL 391511, at *4 (S.D.W. Va. Jan. 27, 2010) (applying preliminary injunction standard to TRO assessment). Faced with an erroneous and wrongful immediate suspension of its Registration, OHHP faces near certain closure, and the community of Oak Hill would be deprived of one of the few pharmacies willing to fill necessary prescriptions to help opioid dependent West Virginians.

A. OHHP is likely to succeed on the merits because the Administrator's immediate suspension is fatally erroneous in multiple respects.

The Administrator's immediate *ex parte* suspension suffers from three insurmountable errors: (1) the preliminary finding was factually incorrect and (2) the stated bases of the suspension were insufficient and inaccurate.[4] Those separate and independently sufficient errors demonstrate that OHHP will likely succeed on demonstrating that the Administrator has not met the standard for immediate suspension in 21 U.S.C. § 824(d).

1. The Administrator's Preliminary Immediate Suspension Finding is factually incorrect and totally unsupportable.

[4] In its Petition to Dissolve, OHHP provided a third contention in support of dissolving the DEA's immediate suspension of OHHP's Registration — that the suspension was not sufficiently tailored to the Administrator's allegations. *See* OHHP's Pet. to Dissolve, ECF 1, at 13, 16-17. Although OHHP stands by that contention, reiterates and incorporates it herein, OHHP maintains that the two bases provided above are sufficient to justify granting the TRO.

The Administrator's Preliminary Immediate Suspension Finding relates facts that are not, and cannot be, correct. By doing so, the Administrator failed to demonstrate that there "is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in absence of an immediate suspension of the registration." *See* 21 U.S.C. § 824(d)(2). Thus, the Administrator's Preliminary Immediate Suspension Finding fails to meet the statutory standard for an immediate *ex parte* suspension of a registration, and the immediate suspension of OHHP's Registration must be dissolved.

In declaring its preliminary finding for the immediate suspension, the Administrator relied upon a totally unsupported falsity. The immediate suspension rests entirely upon the preliminary finding that there was "the substantial likelihood that OHHP will continue to unlawfully *prescribe* controlled substances, thereby allowing the diversion of controlled substances." *See* Exhibit 2, at 12 (emphasis added). But OHHP has *never prescribed* a medication. *See* Exhibit 3, at ¶ 5. OHHP is a pharmacy that *fills* prescriptions. *See id.* Doctors or licensed practitioners are the only people who can *prescribe* medication. *See* 21 U.S.C. § 802(56) (explaining that pharmacies fill or dispense prescriptions for controlled substances and practitioners issue prescriptions). Due to that fundamental falsity — that is, the entire rationale that supported the immediate suspension — the Preliminary Immediate Suspension Finding is grossly insufficient. Based upon that basic error alone, the immediate suspension should be dissolved and OHHP's Registration reinstated.

But that preliminary finding is not the only error; the allegations underlying the fundamentally incorrect finding are also just wrong. As outlined above in section I.E. of this memorandum, the Ex Parte Suspension Order asserted facts that were incorrect, which the DEA knew or should have known, based on its own information. Based on the inaccurate (or simply

stated, false) allegations contained within the Ex Parte Suspension Order, OHHP's TRO should be granted.

2. The stated bases of the Ex Parte Suspension Order fail to satisfy the statutory standard for an immediate *ex parte* suspension of OHHP's Registration.

In addition to the insufficiency of the Administrator's Preliminary Immediate Suspension Finding and the factual allegations underlying it, the supposed red flags that undergird the immediate suspension of OHHP's Registration fail to support that suspension. The red flags alleged by the Administrator fall into three buckets: (1) distance; (2) medication; (3) and private payment of partial prescription fills. But those allegations of supposed red flags of diversion do not acknowledge the on-the-ground circumstances that exist in West Virginia, which force patients to travel extended distances, receive Subutex prescriptions, and pay for those prescriptions privately and in the smaller increments of partial fills.

Those supposed red flags are not, in actuality, "highly indicative of abuse and diversion." *See* Exhibit 2, at 10. Instead, those circumstances are a product of a lack of MAT providers and pharmacies who would fill MAT prescriptions. Thus, patients seeking help with their opioid dependence were forced to travel to Pennsylvania to receive treatment. And when those patients returned with duly written prescriptions, they were often turned down by local pharmacies that would not fill Subutex due to the stigma of treating patients who suffer from addiction. *See* Exhibit 3, at ¶ 12. Sometimes, even if a local pharmacy would fill such a prescription, the patients steered clear, fearing that they would become the object of stigma or ridicule in their small communities due to their MAT prescription. Moreover, Subutex is an appropriate MAT prescription that is FDA-approved for treatment of opioid use disorder and is also more affordable than Suboxone. *See id.* at ¶¶ 3-4. Although more affordable, patients were still forced to pay privately for those

prescriptions because of a lack of insurance coverage and often had to purchase partial fills of their prescriptions due to the inability to afford the whole prescription at one time. *See id.* at ¶ 19. Those circumstances are not indicative of abuse or diversion, but are instead indicative of perseverance and hardship.

Based on his misapprehension of, and disregard for, the factual circumstances surrounding MAT therapy, the Administrator failed to provide a sufficient basis for a "substantial likelihood" determination. *See Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (explaining that agency findings are insufficient where they fail to consider an important aspect of an issue). The "substantial likelihood" standard, as implemented in federal statutes, is a "more stringent" standard. *See Radol v. Thomas*, 772 F.2d 244, 253 (6th Cir. 1985) (differentiating substantial likelihood standard within the context of federal securities statutory structure). That standard is not satisfied by a mere possibility or conceivability that something was likely to occur. *See id.* Where each of the potential indications of abuse or diversion not only has an explanatory justification, but is also a creation of a totally inadequate system for treating the many West Virginians who struggle with opioid use disorder, the Administrator has failed to meet the more stringent standard of substantial likelihood. *See Bates Drug Stores, Inc. v. Holder*, No. CV-11-0167-EFS, 2011 WL 1750066, at *3 (E.D. Wash. May 6, 2011) (recognizing in context of temporary restraining order application that that DEA is unlikely to establish "imminent danger to public health or safety" without evidence that a controlled substance was dispensed to improper individual, for an improper purpose, or in an improper dosage); *see also Holiday CVS, L.L.C. v. Holder*, 839 F.Supp.2d 145, 163 (D.D.C. 2012), *vacated on other grounds by*, 493 Fed. App'x 108 (D.C. Cir. Nov. 26, 2012) (denying preliminary injunction of immediate suspension where "the pharmacists [had] admitted" to failing "to detect warning signs [of abuse]"). Thus, the

Administrator has not satisfied the showing for issuing an immediate *ex parte* suspension of OHHP's Registration. That suspension should be dissolved, and OHHP's Registration should be reinstated pending the final order of the separate administrative proceedings regarding the Show Cause Finding pursuant to § 824(c).

B. OHHP will suffer irreparable harm absent a TRO because it will be forced to shut down as a business.

Without relief by this Court, OHHP will most certainly close in the near future, and thus the second prong for a TRO is satisfied. OHHP has already had to lay off most of its employees. *See* Exhibit 3, at ¶ 22. OHHP has also had to take on debt just to keep the lights on, for now. *See id.* And without the ability to fill controlled medications, OHHP will continue to lose patients and will have to shut its doors. *See id.* Moreover, monetary damages will not be able to compensate OHHP for having to close its doors for good. In other words, OHHP meets the irreparable harm prong. *See NaturaLawn of Am., Inc. v. West Group, LLC*, 484 F.Supp.2d 392, 401 (D. Md. 2007) (finding irreparable harm where plaintiff's operations would be effectively shut down).

C. The balance of hardships weighs in favor of granting the TRO.

Likewise, the third prong for a TRO — the balance of hardships — is met. Whereas OHHP will almost certainly go out of business, the DEA does not face a similarly severe hardship. Indeed, the administrative proceedings to determine whether OHHP's Registration should be revoked will continue and will not be hindered by this Court's action. In those proceedings, the DEA will have the opportunity to demonstrate that OHHP's Registration is inconsistent with the public interest. And OHHP will have a similar opportunity to rebut that effort. In essence, the DEA does not face a hardship if this Court enjoins and dissolves the immediate suspension. The balance of hardships weighs heavily in favor of dissolving the immediate suspension.

D. The TRO is in the public interest because OHHP serves a vital and important role in the Oak Hill community.

Finally, the fourth prong is similarly fulfilled; the public interest weighs in favor this Court granting OHHP's request for a TRO to dissolve the immediate suspension. Like many small West Virginia communities, Oak Hill lacks an abundance of pharmacies. *See* Exhibit 3, at ¶ 1. Indeed, OHHP serves a critical role in the community by providing a local pharmacy where members of that small community can fill their needed prescriptions. Without OHHP, patients in Oak Hill and the surrounding area would be deprived of an important link in the chain of their medical treatment. Therefore, the public interest favors granting the TRO.

III. CONCLUSION

The Administrator failed to meet the statutory standard for immediately suspending OHHP's Registration. The Administrator relied on insufficient bases and reached a plainly false preliminary finding, based largely on factual allegations which the Administrator knew or should have known to be false. Because OHHP satisfies the four prongs for a TRO, this Court must correct the Administrator's mistake and dissolve the *ex parte* suspension order.

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